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Display Date	3-30-00
Publication Date	3-31-00
Certifier	M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

1467 '00 MAR 30 A7:57

21 CFR Parts 864, 866, 870, 872, 874, 876, 878, 884, 886, and 888

[Docket No. 99N-0035]

Medical Devices; Reclassification of 28 Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying 28 preamendments devices from class III (premarket approval) into class II (special controls). FDA is also identifying the special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being undertaken on the agency's own initiative based on new information under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 and the FDA Modernization Act of 1997. The agency is also revising the identification of six of the devices subject to this rule to more accurately reflect the characteristics of devices actually being marketed. FDA is withholding action on 11 devices, which the agency proposed to reclassify, pending further action.

DATES: This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. FDA invited interested persons to comment on the proposed rule by June 14, 1999.

FDA received one request to reopen the comment period for six devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's Good Guidance Practices (GGP's). The request further said that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the requestor asked that FDA extend the comment period until at least 90 days after the guidance documents are publicly available.

FDA agrees with the request. FDA has also identified an additional three devices for which FDA had not issued the guidance documents proposed as special controls in accordance with the GGP policy. Therefore, FDA is withholding action on the devices listed in table 1 of this document at this time. FDA will make the guidance documents for these devices available for comment through the GGP process and will reopen the comment period on the reclassification of these devices when the guidance documents are available.

FDA also received a request for an extension of the comment period for the cutaneous oxygen monitor (§ 868.2500 (21 CFR 868.2500)) on behalf of a foreign manufacturer. The manufacturer needed additional time to translate the proposed special controls documents to prepare their comments. FDA granted this request and will withhold action on this device and reopen the comment period.

TABLE 1.—DEVICES NOT SUBJECT OF THIS RECLASSIFICATION

21 CFR Section	Device Name
868.1150	Indwelling blood carbon dioxide partial pressure (Pco ₂) analyzer
868.1170	Indwelling blood hydrogen ion concentration (pH) analyzer
868.1200	Indwelling blood oxygen partial pressure (Po ₂) analyzer
868.2500	Cutaneous oxygen monitor
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3620	Pacemaker lead adaptor
870.3800	Annuloplasty ring
870.4230	Cardiopulmonary bypass defoamer

TABLE 1.—DEVICES NOT SUBJECT OF THIS RECLASSIFICATION—Continued

21 CFR Section	Device Name
870.4260	Cardiopulmonary bypass arterial blood line filter
870.4350	Cardiopulmonary bypass oxygenator

II. Comments

FDA received five comments on the proposal. The following is a summary of the comments and FDA's response:

(Comment 1) One comment supported the proposal to reclassify four orthopedic devices: The elbow joint metal/polymer constrained cemented prosthesis (§ 888.3150 (21 CFR 888.3150)), the knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540 (21 CFR 888.3540)), the shoulder joint metal/polymer non-constrained cemented prosthesis (§ 888.3650 (21 CFR 888.3650)), and the shoulder joint metal/polymer semi-constrained cemented prosthesis (§ 888.3660 (21 CFR 888.3660)).

FDA agrees with this comment.

(Comment 2) One comment supported the proposed reclassification and special controls for the tinnitus masker (§ 874.3400 (21 CFR 874.3400)).

FDA agrees with this comment.

(Comment 3) A third comment addressed the vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450).

As noted above, FDA is withholding action on this device, until the proposed guidance document intended to be a special control is made available for comment. FDA will address this comment when it takes final action on this device.

(Comment 4) One manufacturer agreed with the proposal to reclassify the over-the-counter (OTC) denture cushion or pad (§ 872.3540 (21 CFR 872.3540)) but recommended that it be reclassified from class III into class I. The manufacturer submitted data on the device to support the claim that general controls are adequate to provide reasonable assurance of the safety and

effectiveness of the device. The comment agreed that proper labeling is important to control risks to health associated with the use of this device.

FDA disagrees with this comment. FDA believes it is necessary that consumers have appropriate directions for use to correctly prepare denture material for a properly fitted denture. The guidance document describes the information necessary to provide reasonable assurance of the safe and effective use of the OTC dental pad or cushion. In particular, it includes descriptive information on the indications for use, contraindications, cautions, and potential adverse effects for the device, as well as the directions for use information regarding adequate mixing, preparation, and use of the product. The guidance document also provides ways that a manufacturer can establish that there is reasonable assurance that an OTC denture cushion or pad with a new intended use, chemical composition, labeling claims, or method of preparation is safe and effective.

(Comment 5) One comment raised three issues concerning the proposed reclassification of the high permeability hemodialysis system (§ 876.5860 (21 CFR 876.5860)) as follows:

1. The comment recommended changing the name and the section heading of § 876.5860 to include three additional therapies: Hemofiltration, hemoconcentration, and hemodiafiltration.

FDA notes that it has cleared these three additional renal therapies identified by the comment under § 876.5860. FDA will not revise the name of the device but it will revise the first sentence of the identification section (§ 876.5860(a)) as follows: “A high permeability hemodialysis system is a device intended for use as an artificial kidney system for treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration.”

2. The comment also recommended further revising the identification of the high permeability hemodialysis system to state that the hemofiltration, hemoconcentration, and hemodiafiltration ultrafiltration coefficient (K_{uf}) should be changed from “greater than 12 ml/hr/mmHg” to “greater than 8 ml/hr/mmHg”.

FDA agrees with the comment with the provision that the bovine or expired human blood be used to measure the K_{uf} . In the final rule, § 876.5860(a)(1) is revised to read:

The hemodialyzer consists of a semipermeable membrane with an *in vitro* ultrafiltration coefficient (K_{uf}) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance.

3. The comment also recommended that any revisions to the hemodialysis-related guidance documents be implemented as Level 1 guidance documents under FDA's GGP's.

FDA will follow its GGP's in issuing revisions to guidance documents used as special controls for this device as well as for all devices.

(Comment 6) FDA also made the following changes on its own initiative for accuracy and clarity:

1. FDA incorrectly cited the title of its biocompatibility guidance and is correcting the title of the guidance to read, "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing'." The special control is the FDA guidance document and not the ISO consensus standard itself.

2. In § 874.3930—*Tympanostomy tube with semipermeable membrane* (21 CFR 874.3930), FDA deleted the proposed special controls except the device specific guidance document. FDA believes that the guidance document adequately addresses the other proposed special controls.

3. In § 876.4480—*Electrohydraulic lithotripter* (21 CFR 876.4480), FDA deleted the proposed special controls except the device specific FDA guidance document. FDA believes that the guidance document adequately addresses the other proposed special controls.

4. In § 876.5860—*High permeability hemodialysis system*, FDA deleted the American National Standards Institute (ANSI)/Association for the Advancement in Medical Instrumentation (AAMI) and United States Pharmacopeia (USP) standards because FDA believes that these standards are adequately addressed in the FDA sterility guidance.

5. In § 884.1060—*Endometrial aspirator* (21 CFR 884.1060); 21 CFR 884.1110—*Endometrial brush*; and § 884.1185—*Endometrial washer* (21 CFR 884.1185), FDA clarified the wording of the labeling and design and testing special controls.

6. In § 884.4100—*Endoscopic electrocautery and accessories* (21 CFR 884.4100), and § 884.4150—*Bipolar endoscopic coagulator-cutter and accessories* (21 CFR 884.4150), FDA added the complete titles and years of the standards and clarified the labeling and treatment instructions. In the preamble to the proposed rule, FDA identified the sterility guidance as a special control for these two devices but did not include it in the regulatory text. FDA has included the sterility guidance in the regulatory text of the final rule.

7. In some device identifications, FDA made minor editorial changes.

III. FDA's Conclusion

FDA has concluded, based on a review of the available information, that the special controls identified in tables 2 and 3 of this document provide reasonable assurance of the safety and effectiveness of these 28 devices. The two tables summarize the special controls to be applied to each device.

TABLE 2.—SUMMARY OF FDA GUIDANCE SPECIAL CONTROLS LISTED BY DEVICE

21 CFR Section	Device Name	FDA Sterility Review Guidance ¹	FDA Biocompatibility Guidance ²	Other FDA Guidance
864.7250	Erythropoietin Assay			3
864.7300	Fibrin monomer paracoagulation test			4
870.3375	Cardiovascular intravascular filter	X	X	5
872.3540	OTC denture cushion or pad		X	6
872.3560	OTC denture reliner		X	6
872.3570	OTC denture repair kit		X	6
872.3600	Partially fabricated denture kit		X	6
874.3930	Tympanostomy tube with semipermeable mem- brane			7
876.4480	Electrohydraulic lithotripter			8
876.5860	High permeability hemodialysis system		X	9,10,11,12
876.5955	Peritoneo-venous shunt	X	X	
878.3610	Esophageal prosthesis			13
878.3720	Tracheal prosthesis			13
884.1060	Endometrial aspirator	X	X	
884.1100	Endometrial brush	X	X	
884.1185	Endometrial washer	X	X	
884.4100	Endoscopic electrocautery and accessories	X	X	14

TABLE 2.—SUMMARY OF FDA GUIDANCE SPECIAL CONTROLS LISTED BY DEVICE—Continued

21 CFR Section	Device Name	FDA Sterility Review Guidance ¹	FDA Biocompatibility Guidance ²	Other FDA Guidance
884.4150	Bipolar endoscopic coagulator-cutter	X	X	14
886.3400	Keratoprosthesis	X	X	15
886.3920	Eye valve implant	X	X	16
888.3150	Elbow joint metal/polymer constrained cemented prosthesis	X	X	17,18,19
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	X	X	17,18,19
888.3650	Shoulder joint metal/polymer non-constrained cemented prosthesis	X	X	17,18,19
888.3660	Shoulder joint metal/polymer semi-constrained cemented prosthesis	X	X	17,18,19

(1) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)"

(2) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,' "

(3) "Document for Special Controls for Erythropoietin Assay Premarket Notification [510(k)s],"

(4) "In Vitro Diagnostic Fibrin Monomer Paracoagulation Test,"

(5) "Guidance for Cardiovascular Intravascular Filters 510(k) Submissions,"

(6) "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits,"

(7) "Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification,"

(8) "Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters,"

(9) "Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers,"

(10) "Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems,"

(11) "Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis,"

(12) "Guidance for Hemodialyzer Reuse Labeling,"

(13) "Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses,"

(14) "Guidance ('Guidelines') for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),"

(15) "Guidance on 510(k) Submissions for Keratoprosthesis,"

(16) "Aqueous Shunt-510(k) Submissions,"

(17) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"

(18) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components," and

(19) "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices."

TABLE 3.—OTHER SPECIAL CONTROLS LISTED BY DEVICE

21 CFR Section	Device Name	Labeling	Standards	Design and Performance Testing
866.3510	Rubella virus serological reagents		<i>NCCLS</i> ¹ 1/LA6, October 1997, 1/LA18, December 1994, D13, October 1993, EP5, February 1999, EP10, May 1998. <i>CDC</i> ² Low Titer Rubella Standard, Reference Panel of Well Characterized Rubella Sera. <i>WHO</i> ³ Rubella Standard.	The maximum pulse amplitude should not exceed 200 mA. The maximum pulse duration should not exceed 50 msec.
870.5550	External transcutaneous cardiac pacemaker (noninvasive)		<i>ANSI/AAMI</i> ⁴ DF-2	
872.6080	Airbrush		<i>IEC</i> ⁵ 60601-1-AM2 (1995-03), Amendment 2	
874.3400	Tinnitus masker	Patient labeling re: hearing health care professional diagnosis, fitting and followup care; risks; benefits; warnings; and specifications.		

TABLE 3.—OTHER SPECIAL CONTROLS LISTED BY DEVICE—Continued

21 CFR Section	Device Name	Labeling	Standards	Design and Performance Testing
876.5955	Peritoneo-venous shunt			Backflow specifications to prevent reflux of blood into the shunt.
884.1060	Endometrial aspirator	INDICATION: Only to evaluate the endometrium. CONTRAINDICATIONS: pregnancy, history of recent uterine perforation, and recent cesarean section.		Sampling component is covered within the vagina.
884.1100	Endometrial brush	INDICATION: Only to evaluate the endometrium. CONTRAINDICATIONS: Pregnancy, history of recent uterine perforation, and recent cesarean section.		Sampling component is covered within the vagina. Adherence of bristles and brush head.
884.1185	Endometrial washer	INDICATION: Only to evaluate the endometrium. CONTRAINDICATIONS: Pregnancy, history of recent uterine perforation, and recent cesarean section. Warning: Do not attach to wall or any external suction.		Maximum intrauterine pressure should not exceed 50 millimeters of mercury. Sampling component is covered within the vagina
884.4100	Endoscopic electrocautery and accessories	INDICATION: For female tubal sterilization. INSTRUCTIONS FOR USE: Destroy at least 2 cm of the fallopian tube; Use a cut (or undampened sinusoidal) wave form; and Use a minimum power of 25 watts. For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.	ANSI/AAMI HF-18 IEC 60601-1-1-AM2 (1995-03) Amendment 2	
884.4150	Bipolar endoscopic coagulator-cutter	INDICATION: For female tubal sterilization. INSTRUCTIONS FOR USE: Destroy at least 2 cm of the fallopian tube; Use a cut (or undampened sinusoidal) wave form; and Use a minimum power of 25 watts. For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.	ANSI/AAMI HF-18 IEC 60601-1-1-AM2 (1995-03) Amendment 2	

TABLE 3.—OTHER SPECIAL CONTROLS LISTED BY DEVICE—Continued

21 CFR Section	Device Name	Labeling	Standards	Design and Performance Testing
888.3150	Elbow joint metal/polymer constrained cemented prosthesis		<i>ASTM</i> ⁶ F 75-92, F 648-98, F 799-96, F 981-93, F 1044-95, F 1108-97, F 1147-95, F 1537-94. <i>ISO</i> ⁷ 5832-3,4, & 12:1996, 5833:1992, 5834-2:1998, 6018:1997, 9001:1994, 14630:1997.	
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis		<i>ASTM</i> F 75-92, F 648-98, F 799-96, F 1044-95, F 1108-97, F 1147-95, F 1537-94, F 1672-95. <i>ISO</i> 5832-3,4, & 12:1996, 5833:1992, 5834-2:1998, 6018:1987, 7207-2:1998, 9001:1994.	
888.3650	Shoulder joint metal/polymer non-constrained cemented prosthesis		<i>ASTM</i> F 75-92, F 648-98, F 799-96, F 1044-95, F 1108-97, F 1147-95, F-1378-97, F 1537-94. <i>ISO</i> 5832-3,4 & 12:1996, 5833:1992, 5834-2:1998, 6018:1987, 9001:1994.	
888.3660	Shoulder joint metal/polymer semi-constrained cemented prosthesis		<i>ASTM</i> F 75-92, F 648-98, F 799-96, F 1044-95, F 1108-97, F 1147-95, F 1378-97, F 1537-94. <i>ISO</i> 5832-3,4 & 12:1996, 5833:1992, 5834-2:1998, 6018:1987, 9001:1994.	

¹National Committee for Clinical Laboratory Standards, 940 West Valley Rd., suite 1400, Wayne, PA 19087, 610-688-0100, <http://www.ncccls.org>.

²Centers for Disease Control and Prevention, Mail Stop G18, 1600 Clifton Rd. NE., Atlanta, GA 30333.

³World Health Organization International Laboratory for Biological Standards, Statens Seruminstitut, Center for Prevention and Control of Infectious Diseases and Congenital Disorders, 5 Artillerivej, DK-2300 Copenhagen S, Denmark.

⁴American National Standards Institute and Association for the Advancement of Medical Instrumentation, 11 West 42d St., New York, NY 10036.

⁵International Electrotechnical Commission, AT3, Rue de Varembe, P.O. Box 131, Geneva, Switzerland CH-1211, <http://www.iec.ch>.

⁶American Society for Testing and Materials, Customer Services, 100 Barr Harbor Dr., West Conshohocken, PA 19428.

⁷ International Organization for Standardization, Case Postale, Geneva, Switzerland CH-1121.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of these devices from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act. Moreover, compliance with special controls proposed for these devices will not impose significant new costs on affected manufacturers as most of these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this rule will not have a significant

economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Parts 870, 872, 874, 876, 878, 884, and 888

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 864, 866, 870, 872, 874, 876, 878, 884, 886, and 888 are amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 864.7250 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 864.7250 Erythropoietin assay.

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(b) *Classification.* Class II. The special control for this device is FDA's "Document for Special Controls for Erythropoietin Assay Premarket Notification (510(k)s)."

3. Section 864.7300 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 864.7300 Fibrin monomer paracoagulation test.

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(b) *Classification.* Class II. The special control for this device is FDA's "In Vitro Diagnostic Fibrin Monomer Paracoagulation Test."

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

4. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Section 866.3510 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 866.3510 Rubella virus serological reagents.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) National Committee for Clinical Laboratory Standards':

(i) 1/LA6 "Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Speciment Handling, and Use of the Test Products in the Clinical Laboratory, October 1997,"

(ii) 1/LA18 “Specifications for Immunological Testing for Infectious Diseases, December 1994,”

(iii) D13 “Agglutination Characteristics, Methodology, Limitations, and Clinical Validation, October 1993,”

(iv) EP5 “Evaluation of Precision Performance of Clinical Chemistry Devices, February 1999,” and

(v) EP10 “Preliminary Evaluation of the Linearity of Quantitative Clinical Laboratory Methods, May 1998,”

(2) Centers for Disease Control’s:

(i) Low Titer Rubella Standard,

(ii) Reference Panel of Well Characterized Rubella Sera, and

(3) World Health Organization’s International Rubella Standard.

PART 870—CARDIOVASCULAR DEVICES

6. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

7. Section 870.3375 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.3375 Cardiovascular intravascular filter.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) “Use of International Standards Organization’s ISO 10993 ‘Biological Evaluation of Medical Devices Part I: Evaluation and Testing,’ ” and

(2) FDA’s:

(i) “510(k) Sterility Review Guidance and Revision of 2/12/90 (K90–1)” and

(ii) “Guidance for Cardiovascular Intravascular Filter 510(k) Submissions.”

8. Section 870.5550 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) “American National Standards Institute/American Association for Medical Instrumentation’s DF-21 ‘Cardiac Defibrillator Devices’ ” 2d ed., 1996, and

(2) “The maximum pulse amplitude should not exceed 200 milliamperes. The maximum pulse duration should not exceed 50 milliseconds.”

PART 872—DENTAL DEVICES

9. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

10. Section 872.3540 is amended by revising paragraph (b)(2) and by removing paragraph (c) to read as follows:

§ 872.3540 OTC denture cushion or pad.

* * * * *

(b) * * *

(2) Class II if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (b)(1) of this section. The special controls for this device are FDA’s:

(i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical—Devices Part I: Evaluation and Testing,’ ” and

(ii) “OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.”

11. Section 872.3560 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 872.3560 OTC denture reliner.

* * * * *

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' " and

(2) "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits."

12. Section 872.3570 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 872.3570 OTC denture repair kit.

* * * * *

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' " and

(2) "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits."

13. Section 872.3600 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 872.3600 Partially fabricated denture kit.

* * * * *

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' " and

(2) "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits."

14. Section 872.6080 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 872.6080 Airbrush.

* * * * *

(b) *Classification.* Class II. The special control for this device is International Electrotechnical Commission's IEC 60601-1-AM2 (1995-03), Amendment 2, "Medical Electrical Equipment—Part 1: General Requirements for Safety."

PART 874—EAR, NOSE, AND THROAT DEVICES

15. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

16. Section 874.3400 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 874.3400 Tinnitus masker.

* * * * *

(b) *Classification.* Class II. The special control for this device is patient labeling regarding:

- (1) Hearing health care professional diagnosis, fitting of the device, and followup care,
- (2) Risks,
- (3) Benefits,
- (4) Warnings for safe use, and
- (5) Specifications.

17. Section 874.3930 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 874.3930 Tympanostomy tube with semipermeable membrane.

* * * * *

(b) *Classification*. Class II. The special control for this device is FDA's "Tympanostomy Tubes, Submission Guidance for a 510(k)."

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

18. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

19. Section 876.4480 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 876.4480 Electrohydraulic lithotripter.

* * * * *

(b) *Classification*. Class II. The special control for this device is FDA's "Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters."

20. Section 876.5860 is revised to read as follows:

§ 876.5860 High permeability hemodialysis system.

(a) *Identification*. A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system (§ 876.5820), the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and

monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices:

(1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient (K_{uf}) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance.

(2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.).

(3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Device—Part I: Evaluation and Testing,' "

(2) "Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers,"

(3) "Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems,"

(4) "Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis," and

(5) "Guidance for Hemodialyzer Reuse Labeling."

21. Section 876.5955 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 876.5955 Peritoneo-venous shunt.

* * * * *

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices' Part I: Evaluation and Testing,' "

(2) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)," and

(3) Backflow specification and testing to prevent reflux of blood into the shunt.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

22. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

23. Section 878.3610 is revised to read as follows:

§ 878.3610 Esophageal prosthesis.

(a) *Identification.* An esophageal prosthesis is a rigid, flexible, or expandable tubular device made of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) *Classification.* Class II. The special control for this device is FDA's "Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses."

24. Section 878.3720 is revised to read as follows:

§ 878.3720 Tracheal prosthesis.

(a) *Identification.* The tracheal prosthesis is a rigid, flexible, or expandable tubular device made of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree. It may be unbranched or contain

one or two branches. The metal tracheal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) *Classification*. Class II. The special control for this device is FDA's "Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses."

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

25. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

26. Section 884.1060 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 884.1060 Endometrial aspirator.

* * * * *

(b) *Classification*. Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' " and

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1),"

(2) Labeling:

(i) Indication: Only to evaluate the endometrium, and

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(3) The sampling component is covered within vagina.

27. Section 884.1100 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 884.1100 Endometrial brush.

* * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' " and

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1),"

(2) Labeling:

(i) Indication: Only to evaluate the endometrium, and

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(3) Design and testing:

(i) The sampling component is covered within the vagina, and

(ii) For adherence of the bristles and brush head.

28. Section 884.1185 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 884.1185 Endometrial washer.

* * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Organization for Standardization's ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' " and

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1),"

(2) Labeling:

(i) Indication: Only to evaluate the endometrium,

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(iii) Warning: Do not attach to a wall or any external suction, and

(3) Design and Testing:

(i) The sampling component is covered within the vagina, and

(ii) Intrauterine pressure should not exceed 50 millimeters of mercury.

29. Section 884.4100 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 884.4100 Endoscopic electrocautery and accessories.

* * * * *

(b) *Classification*. Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(ii) "510(k) Sterility Review Guidance 2/12/90 (K-90)," and

(iii) "Guidance ('Guidelines') for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),"

(2) International Electrotechnical Commission's IEC 60601-1-AM2 (1995-03), Amendment 2, "Medical Electrical Equipment—Part 1: General Requirements for Safety,"

(3) American National Standards Institute/American Association for Medical Instrumentation's HF-18, 1993, "Electrosurgical Devices,"

(4) Labeling:

(i) Indication: For female tubal sterilization, and

(ii) Instructions for use:

(A) Destroy at least 2 centimeters of the fallopian tubes,

(B) Use a cut or undampened sinusoidal waveform,

(C) Use a minimum power of 25 watts, and

(D) For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.

30. Section 884.4150 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(ii) "510(k) Sterility Review Guidance 2/12/90 (K-90)," and

(iii) "Guidance ('Guidelines') for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),"

(2) International Electrotechnical Commission's IEC 60601-1-AM2 (1995-03), Amendment 2, "Medical Electrical Equipment—Part 1: General Requirements for Safety,"

(3) American National Standards Institute/American Association for Medical Instrumentation's HF-18, 1993, "Electrosurgical Devices,"

(4) Labeling:

(i) Indication: For female tubal sterilization, and

(ii) Instructions for use:

(A) Destroy at least 2 centimeters of the fallopian tubes,

(B) Use a cut or undampened sinusoidal waveform,

(C) Use a minimum power of 25 watts, and

(D) For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.

PART 886—OPHTHALMIC DEVICES

31. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

32. Section 886.3400 is revised to read as follows:

§ 886.3400 Keratoprosthesis.

(a) *Identification.* A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye that is not a reasonable candidate for a corneal transplant.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(2) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)," and

(3) "Guidance on 510(k) Submissions for Keratoprostheses."

33. Section 886.3920 is revised to read as follows:

§ 886.3920 Aqueous shunt.

(a) *Identification.* An aqueous shunt is an implantable device intended to reduce intraocular pressure in the anterior chamber of the eye in patients with neurovascular glaucoma or with glaucoma when medical and conventional surgical treatments have failed.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(2) "510(k) Sterility Review Guidance of 2/12/90 (K90-1)," and

(3) "Aqueous Shunts—510(k) Submissions."

PART 888—ORTHOPEDIC DEVICES

34. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

35. Section 888.3150 is revised to read as follows:

§ 888.3150 Elbow joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. It is made of alloys, such as cobalt-chromium-molybdenum, or of these alloys and of an ultra-high molecular weight polyethylene bushing. The device prevents dislocation in more than one anatomic plane and consists of two components that are linked together. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing, ' "

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1),"

(iii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"

(iv) "Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,"

(v) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,"

(2) International Organization for Standardization's (ISO):

(i) ISO 5832-3:1996 "Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,"

(ii) ISO 5832-4:1996 "Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,"

(iii) ISO 5832-12:1996 “Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,”

(iv) ISO 5833:1992 “Implants for Surgery—Acrylic Resin Cements,”

(v) ISO 5834-2:1998 “Implants for Surgery—Ultra High Molecular Weight Polyethylene—Part 2: Moulded Forms,”

(vi) ISO 6018:1987 “Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,”

(vii) ISO 9001:1994 “Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,” and

(viii) ISO 14630:1997 “Non-active Surgical Implants—General Requirements,”

(3) American Society for Testing and Materials’:

(i) F 75-92 “Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,”

(ii) F 648-98 “Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,”

(iii) F 799-96 “Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,”

(iv) F 981-93 “Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implant with Respect to Effect of Material on Muscle and Bone,”

(v) F 1044-95 “Test Method for Shear Testing of Porous Metal Coatings,”

(vi) F 1108-97 “Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,”

(vii) F 1147-95 “Test Method for Tension Testing of Porous Metal Coatings,” and

(viii) F 1537-94 “Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.”

36. Section 888.3540 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,'"

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1),"

(iii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"

(iv) "Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices," and

(v) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components," and

(2) International Organization for Standardization's (ISO):

(i) ISO 5832-3:1996 "Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,"

(ii) ISO 5832-4:1996 "Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,"

(iii) ISO 5832-12:1996 "Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,"

(iv) ISO 5833:1992 "Implants for Surgery—Acrylic Resin Cements,"

(v) ISO 5834-2:1998 "Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,"

(vi) ISO 6018:1987 "Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,"

(vii) ISO 7207-2:1998 “Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 2: Articulating Surfaces Made of Metal, Ceramic and Plastic Materials,” and

(viii) ISO 9001:1994 “Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,” and

(3) American Society for Testing and Materials’:

(i) F 75-92 “Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,”

(ii) F 648-98 “Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,”

(iii) F 799-96 “Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,”

(iv) F 1044-95 “Test Method for Shear Testing of Porous Metal Coatings,”

(v) F 1108-97 “Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,”

(vi) F 1147-95 “Test Method for Tension Testing of Porous Metal Coatings,”

(vii) F 1537-94 “Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants,” and

(viii) F 1672-95 “Specification for Resurfacing Patellar Prosthesis.”

37. Section 888.3650 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA’s:

(i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’ ”

(ii) “510(k) Sterility Review Guidance of 2/12/90 (K90-1),”

(iii) “Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,”

(iv) “Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,” and

(v) “Guidance Document for Testing Non-articulating, ‘Mechanically Locked’ Modular Implant Components,”

(2) International Organization for Standardization’s (ISO):

(i) ISO 5832-3:1996 “Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,”

(ii) ISO 5832-4:1996 “Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,”

(iii) ISO 5832-12:1996 “Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,”

(iv) ISO 5833:1992 “Implants for Surgery—Acrylic Resin Cements,”

(v) ISO 5834-2:1998 “Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,”

(vi) ISO 6018:1987 “Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,” and

(vii) ISO 9001:1994 “Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,” and

(3) American Society for Testing and Materials:

(i) F 75-92 “Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,”

(ii) F 648-98 “Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,”

(iii) F 799-96 “Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,”

(iv) F 1044-95 "Test Method for Shear Testing of Porous Metal Coatings,"

(v) F 1108-97 "Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,"

(vi) F 1147-95 "Test Method for Tension Testing of Porous Metal Coatings,"

(vii) F 1378-97 "Specification for Shoulder Prosthesis," and

(viii) F 1537-94 "Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants."

38. Section 888.3660 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' "

(ii) "510(k) Sterility Review Guidance of 2/12/90 (K90-1),"

(iii) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"

(iv) "Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices," and

(v) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,"

(2) International Organization for Standardization's (ISO):

(i) ISO 5832-3:1996 "Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-aluminum 4-vandium Alloy,"

(ii) ISO 5832-4:1996 "Implants for Surgery—Metallic Materials—Part 4: Cobalt-chromium-molybdenum casting alloy,"

(iii) ISO 5832-12:1996 “Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-chromium-molybdenum alloy,”

(iv) ISO 5833:1992 “Implants for Surgery—Acrylic Resin Cements,”

(v) ISO 5834-2:1998 “Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,”

(vi) ISO 6018:1987 “Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,” and

(vii) ISO 9001:1994 “Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,” and

(3) American Society for Testing and Materials’:

(i) F 75-92 “Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,”

(ii) F 648-98 “Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,”

(iii) F 799-96 “Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,”

(iv) F 1044-95 “Test Method for Shear Testing of Porous Metal Coatings,”

(v) F 1108-97 “Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,”

(vi) F 1147-95 “Test Method for Tension Testing of Porous Metal,”

(vii) F 1378-97 "Standard Specification for Shoulder Prosthesis," and

(viii) F 1537-94 "Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants."

Dated: 3/2/00
March 2, 2000

Linda S. Kahan

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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

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